K110135 (pg. 1 of 2)

OCT 14 2011

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Smith & Nephew, Inc.
Summary of Safety and Effectiveness

Submitted by:	Smith & Nephew, Inc. Orthopaedic Division 1450 East Brooks Road Memphis, Tennessee 38116
Date of Summary:	October 10, 2011
Contact Person Manager	Theresa Leister, Regulatory Affairs Project T (901) 399-5899 F (901) 566-7816
Name of Device:	POLARCUP® Dual Mobility System
Common Name:	Acetabular Component
Device Classification Name and Reference:	21 CFR 888.3358 Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis 21 CFR 888.3390 Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis. 21 CFR 888.3350 Hip joint metal/polymer semi-constrained cemented prosthesis.
Device Class:	Class II
Panel Code:	Orthopaedics/87
Product Code:	LPH, KWY, JDI
Predicate Devices:	POLARCUP Dual Mobility System 510(k): K070278 Product Codes: LPH, KWY VERSAFIT Double Mobility System 510(k): K083116 Product Code: MEH

Device Description

The POLARCUP® Dual Mobility System consists of a metal shell and plastic liner (or insert). The inside of the metal shell is polished, and the outside of the plastic liner is able to articulate against this polished surface. This dual mobility design results in higher intra-prosthetic stability to address the treatment of patients with a high risk of dislocation (especially for elderly patients) or patients with

recurrent dislocation. The subject device is identical to the previously cleared POLARCUP® Dual Mobility System with the exception of an increase in the size range and the addition of Highly Crosslinked Polyethylene Liners.

Technological Characteristics

A review of the mechanical data indicates that the POLARCUP® Dual Mobility System is capable of withstanding expected *in vivo* loading without failure.

Intended Use

The POLARCUP® Dual Mobility System is indicated for:

- Advanced degeneration of the hip joint as a result of degenerative, post-traumatic or rheumatoid arthritis.
- Fracture or avascular necrosis of the femoral head
- Failure of previous hip surgery: joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement
- All forms of osteoarthritis
- Patients with hips at risk of dislocation
- Femoral neck fracture or proximal fracture to hip joint

The POLARCUP® Dual Mobility System is intended for single use only and depending on its version is to be implanted either with or without bone cement.

Substantial Equivalence Information

The overall design, materials, and indications for use for the POLARCUP® Dual Mobility System are substantially equivalent to the commercially available predicate devices identified.

Wear Testing, Coating Characterization, Range of Motion Testing, Stress Analysis and Fatigue Properties were evaluated for the determination of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Smith & Nephew, Inc.
Orthopaedic Division
% Ms. Theresa Leister
Regulatory Affairs Project Manager
1450 East Brooks Road
Memphis, Tennessee 38116

OCT 14 2011

Re: K110135
Trade/Device Name: POLARCUP® Dual Mobility System
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: LPH, KWY, JDI
Dated: October 10, 2011
Received: October 13, 2011

Dear Ms. Leister:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Premarket Notification
Indications for Use Statement

510(k) Number (if known): K110135

Device Name: POLARCUP® Dual Mobility System

Indications for Use:

The POLARCUP® Dual Mobility System is indicated for:

- Advanced degeneration of the hip joint as a result of degenerative, post-traumatic or rheumatoid arthritis.
- Fracture or avascular necrosis of the femoral head
- Failure of previous hip surgery: joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement
- All forms of osteoarthritis
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Prescription Use __X__ AND/OR Over-the-Counter Use _____
(Part 21 CFR 801.109) (Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for MXM

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K110135